

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 63 (90/003,489)
Paper No. 52 (90/003,990)

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte NOVAMEDIX LIMITED

Appeal No. 97-2766
Reexamination Control Nos. 90/003,489 and 90/003,990¹

ON BRIEF

¹ Requests filed July 11, 1994 (Control No. 90/003,489) and October 4, 1995 (Control No. 90/003,990) by Kinetic Concepts, Inc. for the reexamination of U.S. Patent No. 4,721,101, issued January 26, 1988, based on Application 06/911,987, filed September 26, 1986. The resulting reexamination proceedings were ordered merged on February 1, 1996 (see Paper No. 18 in Control No. 90/003,489 and Paper No. 8 in Control No. 90/003,990). According to the appellant: Application 06/911,987 is a division of Application 06/889,376, filed August 1, 1986, now U.S. Patent No. 4,696,289, issued September 29, 1987, which is a continuation-in-part of Application 06/763,686, filed August 8, 1985, now U.S. Patent No. 4,614,180, issued September 30, 1986, and reissued as U.S. Patent No. Re. 32,939 on June 6, 1989, based on Application 07/194,438, filed May 16, 1988, and a continuation-in-part of Application 06/794,443, filed November 4, 1985, now U.S. Patent No. 4,614,179, issued September 30, 1986, and reissued as U.S. Patent No. Re. 32,940 on June 6, 1989, based on Application 07/194,519, filed May 16, 1988; Application 06/763,686 is a continuation-in-part of Application 06/621,499, filed June 18, 1984, now abandoned; Application 06/794,443 is a continuation-in-part of Application 06/751,150, filed July 2, 1985, now abandoned, which is a division of Application 06/621,499.

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Before CALVERT, McQUADE and CRAWFORD, Administrative Patent Judges.

McQUADE, Administrative Patent Judge.

DECISION ON APPEAL

Novamedix Limited originally appealed from the Office action dated February 28, 1996 rejecting claims 1 through 16. The appellant has since canceled claims 15 and 16, and amended claims 10 through 12. Thus, this appeal now involves claims 1 through 14, all of the claims presently pending in these merged reexamination proceedings involving U.S. Patent No. 4,721,101. Our decision in this appeal applies to each proceeding.

The record indicates that U.S. Patent No. 4,721,101, as well as related and commonly assigned U.S. Patent Nos. Re. 32,939, Re. 32,940, and 4,696,289, are currently the subject of litigation, styled Novamedix, Ltd. v. Kinetic Concepts, Inc. and KCI New Technologies, Inc., Civil Action No. SA-92-CA-1077, in the United States District Court for the Western District of Texas, San Antonio Division.² The record also indicates

² Kinetic Concepts, Inc. also has requested two reexaminations in each of U.S. Patent Nos. Re. 32,939, Re. 32,940 and 4,696,289. Control Nos. 90/003,487 and 90/003,987 for U.S. Patent No. Re. 32,940 have resulted in the issuance on December 3, 1996 of Reexamination Certificate B1 Re. 32,940. Control Nos. 90/003,486 and 90/003,988 for U.S. Patent No. Re. 32,939 are currently on appeal to this Board (Appeal No. 97-2135). Control Nos. 90/003,488 and 90/003,989 for U.S. Patent No. 4,696,289 also are currently on appeal to this Board (Appeal No. 97-3680).

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that these four patents had been the subject of litigation, styled Novamedix Limited v. NDM Acquisition Corp. et al., Civil Action No. C-3-94-251, in the United States District Court for the Southern District of Ohio, Western Division at Dayton. In the latter case, the court entered a final judgment on consent decreeing, inter alia, that each of the claims in the four patents “is valid and enforceable” (see Paper No. 20 in Control No. 90/003,489 and Paper No. 11 in Control No. 90/003,990).

The invention at issue in the instant appeal relates to an appliance for promoting venous pump action in the leg of a patient. The appliance stimulates a physiological venous pump mechanism in the sole of the foot in a manner which differs from that in which the pump mechanism is stimulated naturally by normal ambulation. As explained by the inventors, Arthur M. N. Gardner and Roger H. Fox,

[w]e have discovered a venous pump mechanism in the sole of the human foot, which under normal walking conditions for the foot, serves to return blood from the leg into the abdomen with no assistance from muscular action; additionally, we have discovered that when this pump mechanism is stimulated in a particular manner which is not analogous to normal walking conditions for the foot, an overall improvement in blood flow specifically includes enhanced arterial flow [patent specification, column 1, lines 44 through 52].

The inventors’ departure from normal ambulatory conditions involves the application of forces to the foot for a holding period of time which is not present in normal ambulation.

Claim 1 is illustrative and reads as follows:

1. A medical appliance, comprising circumferential-tie means adapted to

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peripherally envelop essentially only and to conform generally to the instep region of a foot and to the plantar region of the foot within the span between the ball and heel of the foot, a single inflatable bag adapted for retention within and by said circumferential-tie means, said bag having an active-surface portion longitudinally limited to said span and conformable to the sole of the foot within said span, and means to inflate and deflate said bag in a recurrent cycle wherein single-pulse delivery of inflation pressure is within two seconds, with deflation commencing at termination of single-pulse delivery, the deflation being for such period of time as is necessary for return of blood to the veins of the foot, said last-defined means including means to retain inflation of said bag for a period up to five seconds prior to commencement of deflation.

The prior art references relied upon by the examiner as evidence of obviousness are:

Nicholson et al. (Nicholson)	3,901,221	Aug. 26, 1975
Gardner et al., British Patent Document (Gardner/Fox)	2,141,938	Jan. 9, 1985

Dreiser, French Patent Document ³	2,390,156	Dec. 5, 1978
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Rastgeldi, Selahaddin, "I. Pressure Treatment of Peripheral Vascular Diseases, A Short Historical Review" and "II. Intermittent Pressure Treatment of Peripheral Vascular Diseases, A Survey of Sixteen Years Personal Experience," Opuscula Medica, Supplementum XXVII, pages 3-49, 1972 (Rastgeldi)

Gaskell, P. and Parrott, J. C. W., "The Effect of a Mechanical Venous Pump on the Circulation of the Feet in the Presence of Arterial Obstruction," Surgery, Gynecology & Obstetrics, Volume 146, pages 583-592, April 1978 (Gaskell/Parrott)

Claims 1 through 14 stand rejected under 35 U.S.C. § 103 as follows:

a) claims 1 through 6 as being unpatentable over Gardner/Fox in view of

³ The record in each of the reexamination proceedings contains an English language translation of the Dreiser reference.

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Gaskell/Parrott or Nicholson;

b) claims 1 through 6 as being unpatentable over Gardner/Fox in view of Rastgeldi;

c) claims 7 through 14 as being unpatentable over Gardner/Fox or Dreiser in view of Rastgeldi and Gaskell/Parrott; and

d) claims 7 through 14 as being unpatentable over Dreiser or Rastgeldi in view of Gaskell/Parrott or Nicholson.

Reference is made to the appellant's main, supplemental and reply briefs (Paper Nos. 29, 39 and 39½ in Control No. 90/003,489 and Paper Nos. 19, 31 and 31½ in Control No. 90/003,990) and to the Office action appealed from and the examiner's main answer (Paper Nos. 19 and 32 in Control No. 90/003,489 and Paper Nos. 10 and 24 in Control No. 90/003,990) for the respective positions of the appellant and the examiner with regard to the merits of these rejections.

In rejecting a claim, an examiner bears the initial burden of presenting a factual basis establishing a prima facie case of unpatentability. In re Oetiker, 977 F.2d 1443, 1445-46, 24 USPQ2d 1443, 1444-45 (Fed. Cir. 1990); In re Piasecki, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984). If this burden is met, the burden of coming forward with a showing of facts supporting the opposite conclusion shifts to the applicant. After such rebuttal evidence is submitted, all of the evidence must be considered anew, with patentability being determined on the totality of the record, by a preponderance of

evidence with due consideration to persuasiveness of argument. Of course, if the examiner's initial showing does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent. Id.

With regard to rejections made under 35 U.S.C. § 103, our reviewing court stated in In re Huang, 100 F.3d 135, 138, 40 USPQ2d 1685, 1687-88 (Fed. Cir. 1996):

A claimed invention is unpatentable if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103 (1994). The ultimate determination as to whether or not an invention is obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459, 567 (1966).

Within this framework, the test for obviousness is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F.2d 413, 425-26, 208 USPQ 871, 881-82 (CCPA 1981). A conclusion of obviousness may be based on the common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. In re Bozek, 416 F.2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969). In this regard, skill is to be presumed on the part of the artisan. In re Sovish, 769 F.2d 738, 743, 226 USPQ 771, 774 (Fed. Cir. 1985).

With these principles in mind, we shall not sustain any of the rejections in which

Gardner/Fox is applied as the primary reference.

Gardner/Fox discloses a medical appliance designed to stimulate the physiological venous pump mechanism in the sole of a human foot by replicating the forces applied to the foot during normal ambulatory motion.

Figure 1 illustrates an embodiment of the appliance which includes an inflatable bag 1 shaped to engage only the plantar arch of the foot, a sling 4 for securing the bag to the foot and a pump apparatus 3 for inflating the bag. As explained by Gardner/Fox,

[i]n use of the appliance when secured to a foot as shown in Figure 1, the pump apparatus 3 operates rapidly to inflate the bag 1 which then applies a pumping pressure to the sole 10 of the foot 11, and also urges the ball and heel of the foot away from each other, thus flattening the plantar arch as would occur if the foot 11 was placed on the ground during normal ambulation, thereby stimulating venous blood-flow. A valve arrangement (not shown) in the pump apparatus 3 then allows the bag 1 to deflate whereafter the bag 1 is again inflated, the inflation/deflation cycle being repeated as long as treatment with the appliance is required.

Preferably inflation of the bag 1 is effected in two seconds or less to provide a satisfactory pumping action, while deflation of the bag 1 can take as long as is necessary for the return of blood to the veins of the foot 11.

The treatment thus provided simulates walking on the foot 11, and thereby improves venous blood circulation in a person being treated who would normally be unable to walk or possibly even stand on the foot.

As a modification of the above described appliance, the valve arrangement in pump apparatus 3 can be dispensed with, the pump apparatus serving only for cyclic inflation of the bag, and at least the surface of the bag 1 in contact with the foot 11 being formed with air leakage orifices thereby to be permeable to air, or being made of a material which is inherently permeable to air Such a surface can be provided as will give the required period for deflation of the bag 1 [page 1, lines 77 through 113].

Figures 2 and 3 illustrate an alternative embodiment of the appliance for use within

a plaster cast. In this embodiment, the bag wraps around the foot so as to engage both the plantar arch and the instep.

Gardner/Fox also discloses that either of the foregoing embodiments may be secured to a patient's foot by conventional footwear such as a boot (see page 2, lines 15 through 19).

As acknowledged by the examiner (see, for example, page 5 in the Office action appealed from and page 4 in the main answer), Gardner/Fox does not meet the limitations in independent claims 1 and 2 requiring the claimed appliance to include means to retain inflation of the bag for a period up to five seconds prior to commencement of deflation or the corresponding limitations in independent claims 7 and 10 requiring the claimed appliance to include a cyclically operable automatic means for delivering pressure within the bag in accordance with the criterion of holding a maximum pressure for a period of up to five seconds before dropping the pressure. The examiner's reliance on Gaskell/Parrot, Nicholson and/or Rastgeldi to cure these deficiencies in Gardner/Fox is not well taken.

Gaskell/Parrott discloses a mechanical venous pump for treating severe arterial obstructions in a patient's foot. As described in this reference,

[t]he venous pump consisted of the arrangement illustrated in Figure 1. The foot, covered by a length of stockinette, was inserted into a boot made of a single layer of transparent flexible vinyl plastic sheet. The toe of the boot was fitted with a large metal ring which was made airtight by the insertion of a rubber stopper. The stopper carried tubes for the inflation of the boot and for monitoring pressures. At the ankle, the boot was circled by a pneumatic

cuff shaped to fit [sic, snugly] on a cone. The cuff and the boot were connected to their own individual air pressure reservoirs. To operate the pump, the cuff was first inflated to the pressure desired in the boot. The pressure reservoir serving the boot was then opened with an available pressure above that in the cuff. The boot was quickly inflated to the pressure set by the pressure in the cuff, with the excess flow of air escaping from the boot under the cuff. Both cuff and boot were deflated again after 2 seconds. The pressure on the foot within the boot was thus regulated by the pressure in the cuff. An electronic timer controlled the time and period of inflation of the cuff or boot individually but in a linked and synchronized manner [page 583].

According to Gaskell/Parrott, “[a] brief inflation of the boot empties the veins of the foot, and the venous pressure remains reduced until the veins are refilled by forward flow of blood from the arteries” (page 583). To evaluate the effectiveness of the boot in reducing venous pressure, Gaskell/Parrott tested it using the following variables: “compression pressures, ranging from 40 millimeters of mercury below to 40 millimeters of mercury above the venous pressure at the foot, compression periods of 0.5 to 4.0 seconds in increments of 0.5 second, compression frequencies of once every 5, 10, 15, 20 and 30 seconds” (page 584). Figure 3 depicts the results of tests using different compression pressures wherein “the foot was compressed every 15 seconds for 2 seconds” (page 586). Among other things, Gaskell/Parrott generally found

that a compression pressure several millimeters of mercury higher than the maximum venous pressure at the foot was necessary for most efficient pressure reduction. A compression period of 2 seconds was the minimum at which one could be sure of an adequate pressure reduction, 1 second was often too short and periods longer than 2 seconds were unnecessary and reduced efficiency [pages 587 and 588].

Nicholson discloses a boot for treating circulatory deficiencies in a patient's leg in order to increase the flow of blood through the veins. According to Nicholson, this result can be obtained "by applying pressure through a pressure garment with a rise time of at least 10 mm of mercury per second and a holding time at the level of at least 30 mm of mercury for at least 8 seconds. A cycle period of one minute is near optimum" (column 1, lines 51 through 55). The boot 26 communicates with a pressure tank 30 via hoses 28. The operation of the boot is controlled by a cyclic controller 34 for applying and releasing pressure in accordance with the graph shown in Figure 1. As described by Nicholson,

FIG. 1 is a graph of pressure at the cyclic controller output in accordance with the preferred pressure cycle. When the pressure line is connected to the boot by operation of a valve at time zero, curve portion 10 indicates a rapid rise in less than 4 seconds to greater than 30 mm of mercury. The pressure then climbs gradually above 40 mm of mercury as indicated by curve 11 until 10 seconds is reached at which point the pressurizing valve is closed and the exhaust valve opening to the atmosphere is opened so that at 12 seconds the pressure has dropped below 10 mm as depicted by curve 12. For the following 48 second time period, depicted by curve 14, no pressure is applied allowing the blood veins to refill. The cycle repeats at 60 second intervals [column 2, lines 14 through 27].

As for the pressure inside the boot, Nicholson states:

FIG. 4 shows pressure measured inside a boot during a controller pressure cycle according to FIG. 1. The rise time inside the boot is 40 mm Hg. in approximately 4 seconds as shown in curve 35. The fall time shown by curve 36 is likewise a little slower falling to 10 mm Hg. in about 2 seconds and then curving exponentially to 0 over the next 8 seconds.

While the invention has been described in accordance with a

preferred embodiment, some latitude in the operation of the cycle is desirable depending on specific patients and conditions. A rapid boot pressure rise to at least 30 mm of mercury produces near optimum results when extended over 3 seconds. With particularly sensitive patients, this rise may be extended out to 5 seconds to reduce discomfort. Similarly, the maximum pressure attained is desirably between 40 and 50 mm of mercury, but a peak of 30 mm of mercury is sufficient for most cases. A range of 9 to 15 seconds is acceptable for the time interval between the beginning of pressure application and the onset of pressure release. For maximum effect it is desirable to delay the next application of pressure until the venous flow has returned to its normal equilibrium point, however, this differs with the individual patient and may vary within a fairly wide range with a total period between the cyclical commencement of pressure application being anywhere from about 40 to 80 seconds. A period of 60 seconds is suitable for most cases [column 2, line 67 through column 3, line 26].

Rastgeldi discloses a method and apparatus for treating circulatory conditions such as ischemia by the cyclical application of pressure to a patient's leg (see pages 38 through 43). The method involves the use of a venous occlusion cuff applied about the upper thigh, and cyclically inflatable cuffs applied about the lower thigh, calf and foot. The inflatable cuffs communicate with a source of pressure which functions to (1) inflate the cuffs from 0 mm Hg to a suprasystolic pressure of, for example, 210, 230 or 240 mm Hg, (2) maintain the suprasystolic pressure for holding period of, for example, 5 or 6 seconds, (3) deflate the inflatable cuffs back to 0 mm Hg, and (4) repeat the process at intervals of, for example, 20, 21 or 22 seconds (see Figures 10 through 12).

According to the examiner, it would have been obvious to one of ordinary skill in the art in view of the teachings of Gaskell/Parrot, Nicholson and/or Rastgeldi to provide

appliance disclosed by Gardner/Fox with the inflation retaining or holding features required by independent claims 1, 2, 7 and 10 to improve the circulation of blood (see pages 3 through 7 in the Office action appealed from).

As indicated above, the Gardner/Fox reference pertains to a medical appliance which stimulates the physiological venous pump mechanism in the sole of a human foot by replicating forces applied to the foot during normal ambulatory motion. Thus, it is not surprising that this reference fails to meet the limitations in independent claims 1, 2, 7 and 10 relating to the pressure retaining or holding means since the holding period afforded by such means is not present in normal ambulation according to the appellant's patent specification. Indeed, given the stated objective of the Gardner/Fox appliance and its intended method of use, this reference actually teaches away from an appliance having the pressure retaining or holding means required by claims 1, 2, 7 and 10.

Moreover, the devices and methods disclosed by Gaskell/Parrott, Nicholson and/or Rastgeldi for improving circulation differ substantially from those disclosed by Gardner/Fox. For example, none of these secondary references shares Gardner/Fox's appreciation that a physiological venous pump mechanism exists in the sole of a foot, that this pump mechanism is naturally stimulated by normal ambulatory motion and that the conditions of such ambulatory motion can be simulated by an inflatable device. Although the Rastgeldi device includes an inflatable cuff disposed about the sole and instep of the

foot, Rastgeldi gives no indication that this cuff is even inherently capable of functioning in the manner desired by Gardner/Fox.

In light of the foregoing, it is not apparent, nor has the examiner cogently explained, how or why the combined teachings of Gardner/Fox in view of Gaskell/Parrott, Nicholson and/or Rastgeldi would have suggested the appliance recited in independent claims 1, 2, 7 and 10. We are therefore constrained to conclude that these particular reference combinations fail to establish a prima facie case of obviousness with respect to the subject matter recited in the claims against which they are applied.

We also shall not sustain the standing 35 U.S.C. § 103 rejection of claims 7 through 14 as being unpatentable over Dreiser or Rastgeldi in view of Gaskell/Parrott or Nicholson.

Dreiser discloses a “pressotherapy” boot for applying pressure and decompression to the leg of a patient to treat circulatory insufficiencies (see page 1 in the translation). To this end, the boot includes a plurality of inflatable pockets 1 through 4, each corresponding to a segment of the patient’s leg and having a respective plug or fitting 5 for connection to a source of pressurized air such as a compressor. Pocket 1 corresponds to the thigh, pocket 2 to the calf, pocket 3 to the ankle, and pocket 4 to the sole of the foot “in the region where arterial and venous intersections are very dense” (translation, page 3). Dreiser’s drawings indicate that pocket 4 is shaped for active engagement with the patient’s foot substantially only in the region between the ball and the heel of the foot.

The relevant disclosures of Rastgeldi, Gaskell/Parrott and Nicholson are described above.

As acknowledged by the examiner (see page 8 in the appealed Office action), Dreiser does not meet the limitations in independent claims 7 and 10 relating to the operational criteria of the cyclically operable automatic means for delivering pressure within the bag. Notwithstanding the examiner's finding to the contrary (see page 8 in the Office action appealed from), Rastgeldi does not meet the limitations in claims 7 and 10 requiring the bag to be shaped for active engagement solely with a human foot and substantially only in the region between the ball and heel of the foot. In this regard, Rastgeldi's Figures 10 through 12 show the inflatable foot cuff as engaging the foot completely about its periphery. Given the substantial structural differences between the appliances disclosed by Dreiser and Rastgeldi on one hand and Gaskell/Parrott and Nicholson on the other hand (e.g., discrete inflatable pockets or cuffs for the former versus inflatable boots for the latter), it is not apparent, nor has the examiner cogently explained, how or why the proposed reference combinations of Dreiser or Rastgeldi in view of Gaskell/Parrott or Nicholson would have suggested the appliance recited in independent claims 7 and 10, or in claims 8, 9 and 11 through 14 which depend therefrom. Thus, here again we are constrained to conclude that these reference combinations fail to establish a prima facie case of obviousness with respect to the subject matter recited in claims 7

through 14.

We shall sustain, however, the standing 35 U.S.C. § 103 rejection of independent claims 7 and 10 as being unpatentable over Dreiser in view of Rastgeldi and Gaskell/Parrott. We also shall sustain the standing 35 U.S.C. § 103 rejection of dependent claims 8, 9 and 11 through 14 as being unpatentable over Dreiser in view of Rastgeldi and Gaskell/Parrott since the appellant has not argued such with any reasonable specificity, thereby allowing these dependent claims to stand or fall with parent claims 7 and 10 (see In re Nielson, 816 F.2d 1567, 1572, 2 USPQ2d 1525, 1528 (Fed. Cir. 1987)).

To begin with, and for the reasons discussed above, Gaskell/Parrott would not have suggested modifying the Dreiser device in any way meaningful to the rejection at hand. The examiner's application of Gaskell/Parrott to support this rejection is, at worst, superfluous, with Dreiser and Rastgeldi being sufficient to establish the knowledge and level of ordinary skill in the art necessary to support the examiner's conclusion of obviousness.

The examiner's determination that Dreiser teaches, or would have suggested, a medical appliance meeting all of the limitations in independent claims 7 and 10 except for those relating to the specific operational criteria of the cyclically operable automatic means for delivering pressure within the bag (see pages 6 and 7 in the Office action appealed from) is well founded. In this regard, Dreiser's pocket 4 constitutes an inflatable bag

shaped for active engagement solely with a human foot and substantially only in the region between the ball and heel of the foot, and Dreiser's source of pressurized air for applying pressure and decompression is suggestive of a cyclically operable automatic means for delivering pressure within this bag. The appellant's various arguments that the examiner's determination here is unsound because the Dreiser apparatus involves a boot-like structure and includes additional pockets 1, 2 and 3 is not persuasive because it is not commensurate with the actual scope of claims 7 and 10. As pointed out by the examiner (see page 7 in the answer), neither of these claims contains any limitation which is inconsistent with or excludes the presence of a boot-like structure or additional pockets.

The circulatory treatment device disclosed by Rastgeldi (see Figures 10 through 12) is similar in many respects to that disclosed by Dreiser. The pressure criteria at which Rastgeldi's device is operated are clearly suggestive of the operational criteria set forth in claims 7 and 10. Given Rastgeldi's teaching that such criteria aid in the treatment of circulatory problems, the examiner's conclusion that "[i]t would have been obvious to modify the inflation means taught by . . . Dreiser with the inflation criteria and holding period taught by Rastgeldi" (Office action appealed from, page 7), thereby arriving at the subject matter recited in claims 7 and 10, is well taken.

The appellant's arguments and evidence to the contrary are not persuasive, essentially because they are not commensurate with the relatively broad scope of claims 7

and 10.⁴

More particularly, the appellant's criticism of the Dreiser appliance focuses on its inclusion of a boot-like structure having pockets 1, 2 and 3 in addition to the sole pocket 4 (see, for example, pages 23 through 32 in the main brief). As indicated above, however, claims 7 and 10 do not contain any limitation which is inconsistent with or excludes such elements.

The appellant's contention that Rastgeldi teaches an appliance employing a simple harmonic oscillatory inflation, rather than one having an inflation cycle suggestive of the "holding" limitations in claims 7 and 10 (see, for example, pages 20 and 21 in the main brief), is also unconvincing. Although somewhat lacking in detail, Rastgeldi's description of the appliance shown in Figures 10 through 12 clearly indicates that it operates on an inflation cycle having a "holding" period at the maximum suprasystolic pressure. For example, the description of Figure 10 on page 40 discusses "applying intermittent pressure to the feet, calves, and thighs, oscillating between 16 seconds pressure-free period and 6 seconds suprasystolic pressure of 240 mm Hg." The Gardner/Fox

⁴ The examiner has refused to enter into the record the "Declaration of Mark S. Myerson, M.D." filed December 23, 1996 (Paper No. 35 in Control No. 90/003,489 and Paper No. 26¼ in Control No. 90/003,990) and the "Gardner/Fox Supplemental Declaration under 37 CFR § 1.132" filed February 3, 1997 (Paper No. 35½ in Control No. 90/003,489 and Paper No. 26½ in Control No. 90/003,990), a decision which has been upheld twice on petition to the Commissioner. Accordingly, we have not considered either declaration in evaluating the merits of the appealed rejections.

declaration (Paper No. 24 in Control No. 90/003,489 and Paper No. 16 in Control No. 90/003,990), advanced to support the appellant's position on this point (see pages 20 and 21 in the main brief), does not actually do so. In the declarants' own words, "Rastgeldi's oscillatory inflation must be taken as simple harmonic (*i.e.*, sinusoidal), absent any Rastgeldi indication to the contrary" (page 8, paragraph 11.C.). As discussed above, however, Rastgeldi does provide clear indication to the contrary.

Moreover, Rastgeldi's teaching that the operational criteria disclosed therein aid in the treatment of circulatory problems would have provided the artisan with ample suggestion or motivation to combine Dreiser and Rastgeldi in the manner proposed by the examiner, and thereby refutes the various hindsight arguments made by the appellant.

The evidentiary showings advanced by the appellant to establish non-obviousness by demonstrating, inter alia, willful infringement and copying, unexpected result, commercial success, successful clinical use and public recognition are entitled to little, if any, probative weight with respect to the subject matter recited in independent claims 7 and 10 because they are not commensurate with the actual scope of these claims. More specifically, the showings relate to an appliance which applies pressure only to a patient's foot so as to stimulate the physiological venous pump mechanism therein. This is perhaps best brought out by the following passage from the appellant's patent specification:

[i]n all cases, it is important and deemed significant that neither the distal calf pump nor the proximal calf pump, nor any other of the significant

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pumps of the venous-return system of the involved leg is actuated in time-coincidence with foot-pump actuation. This fact illustratively enables the described invention to be operative within a cast, or to be operative in a region remote from orthopedic fixation of a damaged tibia, knee, or femur, or to be similarly remote from the region of a vein-transplant operation and thus to relatively rapidly dissipate the pain and swelling which are the normally expected post-operative consequence[s] of such an operation. In spite of the remoteness of foot-pump actuation from these other regions of trauma, the fact of no other pump involvements means that foot-pump driven venous return flow can be substantially unimpeded in its direct delivery to and through the region of trauma [column 5, lines 27 through 43].

Claims 7 and 10, however, are not limited to an appliance which applies pressure only to a patient's foot so as to stimulate the physiological venous pump mechanism therein. As should be apparent by now, this breadth in the scope of claims 7 and 10 severely undercuts the position taken by the appellant with regard to the rejection in question.

The appellant also relies on the above mentioned final judgment on consent entered in the Novamedix Limited v. NDM Acquisition Corp. et al. litigation (see Paper No. 20 in Control No. 90/003,489 and Paper No. 11 in Control No. 90/003,990) and the memorandum and recommendation of the court's magistrate judge on opposing Motions for Summary Judgment in the above mentioned Novamedix, Ltd. v. Kinetic Concepts, Inc. and KCI New Technologies, Inc. litigation (see Paper No. 13, Exhibit C, in Control No. 90/003,489) as evidence of non-obviousness. Suffice it to say that neither has any particular pertinence to the issues of obviousness presented by the rejection at issue.

Thus, based on the totality of the evidence and argument of record, the differences

between the subject matter recited in claims 7 and 10 and the prior art combination of Dreiser in view of Rastgeldi are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. As indicated above, dependent claims 8, 9 and 11 through 14 shall fall with parent claims 7 and 10.

In summary, the decision of the examiner:

a) to reject claims 1 through 6 under 35 U.S.C. § 103 as being unpatentable over Gardner/Fox in view of Gaskell/Parrott or Nicholson is reversed;

b) to reject claims 1 through 6 under 35 U.S.C. § 103 as being unpatentable over Gardner/Fox in view of Rastgeldi is reversed;

c) to reject claims 7 through 14 under 35 U.S.C. § 103 as being unpatentable over Gardner/Fox or Dreiser in view of Rastgeldi and Gaskell/Parrott is reversed to the extent that Gardner/Fox is the primary reference, and affirmed to the extent that Dreiser is the primary reference; and

d) to reject claims 7 through 14 under 35 U.S.C. § 103 as being unpatentable over Dreiser or Rastgeldi in view of Gaskell/Parrott or Nicholson is reversed.

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No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

IAN A. CALVERT)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
JOHN P. McQUADE)	
Administrative Patent Judge)	APPEALS AND
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)	INTERFERENCES
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MURRIEL E. CRAWFORD)	
Administrative Patent Judge)	

JPM/caw

Appeal No. 97-2766
Reexamination Control Nos. 90/003,489 and 90/003,990

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